920 KAR 1:060. Protection of human subjects.

RELATES TO: 45 C.F.R. 46.101-46.409, 164.512(i)
STATUTORY AUTHORITY: KRS 194A.050(1), 194A.060(1), 45 C.F.R. 46.101(a)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the secretary to promulgate administrative regulations necessary to implement programs mandated by federal law, or to qualify for receipt of federal funds and necessary to cooperate with other state and federal agencies for the proper administration of the cabinet and its agencies. 45 C.F.R. 46.101(a) requires the cabinet to have an Institutional Review Board for the Protection of Human Subjects to protect the rights and welfare of human subjects involved in research. This administrative regulation establishes specific requirements for protecting human subjects involved in research and incorporates by reference applicable publications that establish additional requirements.

Section 1. Definitions. (1) "Board" or "IRB" means the cabinet's Institutional Review Board required by Section 2 of this administrative regulation.
(2) "Cabinet" is defined by KRS 194A.005(1).
(3) "Principal investigator" means the investigator involved in the research project who has responsibility for making decisions regarding the research study.
(4) "Research" is defined by 45 C.F.R. 46.102(d).

Section 2. Institutional Review Board. (1) An IRB for the Protection of Human Subjects shall be created within the cabinet.
(2) The board shall:
(a) Consist of not less than five (5) nor more than eleven (11) members appointed by the secretary;
(b) Include members from various professional and academic fields including consideration of race, gender, and cultural backgrounds in accordance with 45 C.F.R. 46.107(a);
(c) Include, in accordance with 45 C.F.R. 46.107(c), at least one (1) member each with primary concerns in the following areas:
1. Scientific; and
2. Nonscientific;
(d) Include, in accordance with 45 C.F.R. 46.107(d), at least one (1) member who shall not:
1. Otherwise be affiliated with the cabinet; and
2. Be part of the immediate family of a person who is affiliated with the cabinet;
(e) Include at least one (1) member designated by the secretary to act as a chair; and
(f) Meet as needed to review a project.
(3) The secretary shall appoint an IRB administrator, within a cabinet department or office, who shall:
(a) Serve as liaison between the board and the U.S. Department of Health and Human Services;
(b) Maintain records in accordance with 45 C.F.R. 46.115;
(c) Conduct a preliminary review of a submitted project;
(d) Determine if a project requires board review in accordance with:
1. 45 C.F.R. 46.101;
2. 45 C.F.R. 46.102(d); and
3. Section 3(1) of this administrative regulation.
(e) Refer to the board a project to which this administrative regulation applies; and
(f) Make recommendations to the board on the disposition of an applicable project.

(4) The commissioner or executive director of the department or office in which the IRB Administrator is appointed shall:

(a) Provide administrative support to the board; and

(b) Assign necessary staff.

Section 3. Project Submission. (1) A research project involving a human subject shall be submitted by the principal investigator to the board chair or board staff for review if it:

(a) Is conducted, supported financially, endorsed, or approved by the cabinet;

(b) Uses staff or facilities provided by the cabinet;

(c) Involves a present or former client or beneficiary of the cabinet as a subject because of that relationship with the cabinet;

(d) Involves a present or former employee of the cabinet as a subject because of that relationship with the cabinet; or

(e) Involves a cabinet record relating to a present or former client, beneficiary, or employee of the cabinet.

(2) Project submission shall include the following, if applicable:

(a) A completed "Request for Research Activity Approval, Institutional Review Board for the Protection of Human Subjects (IRB), Kentucky Cabinet for Health and Family Services";

(b) A narrative description of the project's purpose and proposed research procedures;

(c) The research instrument to be used;

(d) A narrative description of how subject confidentiality shall be maintained; and

(e) The research subject consent documents to be used.

(3) Unless first approved by the board, modification in the research protocol or design of an approved research project that may increase the level of risk to a subject shall not be implemented.

(a) If an alteration becomes necessary, the principal investigator shall obtain prior approval of the board.

(b) Failure to obtain prior approval of the board may result in suspension or termination of all research activity, depending on whether the failure to obtain prior approval was willful and the severity of the potential increase of the level of risk to a subject.

Section 4. Board Approval. (1) The board shall review a research project submitted as specified in Section 3(1) of this administrative regulation and not specifically exempted from board review by 45 C.F.R. 46.101(b).

(2) Board approval of a project shall represent a judgment that human subjects are adequately protected, and shall not represent a:

(a) Judgment concerning its ultimate research value; or

(b) Policy decision regarding the value of the research to the cabinet.

(3) Except to provide information requested by the IRB, a member of the board shall not participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest.

(4) A principal investigator may request a reconsideration of an adverse decision by the board by submitting a written request for reconsideration to the chair of the IRB.

(5) The request shall be made within thirty (30) days of the principal investigator's receipt of notification of the adverse decision.

(6) A reconsideration shall be made in the same manner as the initial review.

(7)(a) The IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

(b) These individuals shall not vote with the IRB.

Section 5. Board Responsibilities. The board shall:

(1) In coordination with IRB staff, call a meeting as needed to conduct board business; and

(2) Review and determine disposition of an applicable research project consistent with 45 C.F.R. 46.101 to 46.409.

Section 6. Responsibilities of Principal Investigators. (1) If a change is made in research design or protocol that affects the level of risk to a subject, confidentiality procedures, or consent procedures, the principal investigator shall submit the change, before implementation, to the board for approval.

(2) The principal investigator shall report to the board:

(a) An unanticipated problem involving a risk to a subject or another individual, as a result of research activity, within ten (10) working days; and

(b)1. A research subject death within seven (7) days of the principal investigator's knowledge of a death; and

2. Whether the death appears likely to be related to participation in the research project.

(3) The principal investigator shall submit to the board:

(a) A copy of final research findings and conclusions; and

(b) An annual report and request for reapproval for a research study that extends beyond one (1) year.

Section 7. Confidentiality. (1) Research information that identifies an individual subject shall be regarded as confidential in accordance with KRS 194A.060(1), 45 C.F.R. 46.111(a)(7), and 45 C.F.R. 164.512(i) and shall not be disclosed to a person outside the research project staff or published without the subject's prior written authorization.

(2) Raw or summary data may be released if the data does not identify a subject.

Section 8. References. The decision of the board concerning the protection of a human subject shall be in accordance with:

(1) The "Belmont Report Ethical Principles and Guidelines for the Protection of Human Subjects of Research, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, edition April 18, 1979";

(2) 45 C.F.R. 46.101 through 45 C.F.R. 46.409; and

(3) 45 C.F.R. 164.512(i).

Section 9. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) The "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, edition April 18, 1979"; and

(b) "Request for Research Activity Approval, Institutional Review Board for the Protection of Human Subjects (IRB), Kentucky Cabinet for Health and Family Services, edition 1/07".

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Cabinet for Health and Family Services, IRB Administrator, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. through 4:30 p.m. (25 Ky.R. 2740; Am. 26 Ky.R. 66; eff. 8-18-99; 30 Ky.R. 754; 1294; eff. 11-19-2003; 33 Ky.R. 1743; 2329; eff. 3-1-07.)